FEB - 4 2004

K033969

510(k) Summary

Date	December 19, 2003
Name and Address of Manufacturer	VISTAKON®, Division of Johnson & Johnson Vision Care, Inc., 7500 Centurion Parkway, Suite 100 Jacksonville, FL 32256 Contact: Annette M. Hillring Phone: (904) 443-1808 Fax: (904) 443-1424 Email: ahillring@visus.jnj.com
Identification of Device	Trade Name: ACUVUE® *2 COLOURS*™ Brand (etafilcon A) Soft Hydrophilic Contact Lens with UV Blocker Common or Usual Name: Soft (hydrophilic) Contact Lens (daily wear) Classification: 21 CFR 886.5923 Class II
Predicate Device	ACUVUE® *2 COLOURS*™ Brand (etafilcon A) Soft Hydrophilic Contact Lens with UV Blocker cleared via 510(k)s K024177 on January 22, 2003, and K010114 on April 11, 2001
Device Description	The device description is identical to that cleared under K010114 and K024177.
Intended Use	The intended use is identical to that cleared under K010114 and K024177.
Technological Characteristics	The technological characteristics are identical to those cleared under K010114 and K024177.

Continued on next page

510(k) Summary, Continued

Non-Clinical Studies

As recommended in the *Premarket Notification 510(k) Guidance Documen for Daily Wear Contact Lenses*, May 1994, the following tests were conducted:

A. Toxicology
- USP Ocular Irritation
- USP Systemic Toxicity
- *In-Vitro* Cytotoxicity

B. Chemistry/Leachables
- Formulation and Process
- Physical and Mechanical Properties
- Leachable Monomer and Additives

Clinical Studies

No clinical studies were required to demonstrate the safety and effectiveness of the subject device.

Conclusions

The modified ACUVUE® *2 COLOURS*™ Brand (etafilcon A) Soft Hydrophilic Contact Lens with UV Blocker is substantially equivalent to the ACUVUE® *2 COLOURS*™ Brand (etafilcon A) Soft Hydrophilic Contact Lens with UV Blocker most recently cleared via 510(k) K024177 on January 22, 2003.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Annette M. Hillring
Regulatory Affairs Consultant
VISTAKON
Division of Johnson and Johnson Vision Care, Inc.
7500 Centurion Parkway
Suite 100
Jacksonsville, FL 32256

Re: K033969
Trade/Device Name: ACUVUE® 2 COLOURS™ Brand (etafilcon A) Soft (hydrophilic) Contact Lens with UV Blocker for Daily Wear
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL; MVN
Dated: December 19, 2003
Received: December 22, 2003

Dear Ms. Hillring:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications Statement

510(k) Number (if known):

Device Name: ACUVUE® *2 COLOURS*™ Brand (etafilcon A) Soft Hydrophilic Contact Lens with UV Blocker

Indications For Use:

The ACUVUE® *2 COLOURS* Contact Lenses are indicated for daily wear to enhance or alter the apparent color of the eye and/or for the correction of refractive ametropia (myopia and hyperopia) in aphakic or not aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism. ACUVUE® *2 COLOURS* contact lenses are available in 0.00D for those patients who do not need vision correction but desire the cosmetic benefits of opaque or enhancer cosmetic contact lenses.

The ACUVUE® *2 COLOURS* (etafilcon A) Soft (hydrophilic) BIFOCAL Contact Lens is indicated for daily wear for the correction of distance and near vision in presbyopic, aphakic or not aphakic persons with non-diseased eyes who may have 0.75 D of astigmatism or less.

The ACUVUE® *2 COLOURS* (etafilcon A) Soft (hydrophilic) TORIC Contact Lens is indicated for daily wear for the correction of visual acuity in aphakic or not aphakic persons with non-diseased eyes that are hyperopic or myopic and may have 10.00 D of astigmatism or less.

The ACUVUE® *2 COLOURS* (etafilcon A) Soft (hydrophilic) TORIC-BIFOCAL Contact Lens is indicated for daily wear for the correction of distance and near vision in presbyopic aphakic or not aphakic persons with non-diseased who may have 10.00 D of astigmatism or less.

ACUVUE® *2 COLOURS* UV Blocking Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

The ACUVUE 2 *COLOURS* Contact Lenses may be prescribed for daily wear. Eye Care Practitioners may prescribe the lenses either for single-use disposable wear or frequent/planned replacement wear with cleaning, disinfection and scheduled replacement (see "Wearing Schedule"). When prescribed for frequent/planned replacement wear, the lenses may be disinfected using a chemical disinfection system only.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devices

510(k) Number K033969